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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Sadanobu Shirai

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EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

08/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,858	Applicant(s) SHIRAI ET AL.	
	Examiner HASAN S. AHMED	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' response, filed on 10 July 2009. Applicants' request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claim 1 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

As amended, claim 1 recites the limitation "other than an acrylic adhesive." After carefully examining the instant disclosure, the examiner respectfully submits that support for this amendment is lacking and the addition of said limitation is new matter. Specifically, said limitation is not set forth in the instant specification. The specification, including page 5, lines 4-13, have been carefully reviewed and sufficient support for the limitation "other than an acrylic adhesive" was not found. While the instant specification indicates that acrylic adhesives are not preferred, there is no absolute exclusion indicated, as is currently claimed. According to the specification, "...the patch related to

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the present invention does not need such substances (i.e. acrylic adhesives), and that it is found that to blend such substances in an adhesive layer is not rather preferable because such substances cause to give great influences [sic] to release pattern of turobuterol and stability in changes of the passage with time." See page 5, lines 9-10.

However, the specification does not state that the adhesive resin must be other than an acrylic adhesive, as is currently claimed. Further, the specification does not specify how acrylic adhesives influence the release pattern and stability of tulobuterol with the passage of time. No data to this effect is provided. As such, the newly added limitation is deemed to be new matter.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,254,348 ("Hoffmann") (cited in the IDS of 18 May 2005) in view of U.S. Patent No. 5,866,157 ("Higo") (cited in the PTO-892 of 14 July 2006), further in view of U.S. Patent No. 5,312,627 ("Stroppolo").

Independent claim 1 recites a patch prepared by laminating an adhesive layer consisting of a rubber, an adhesive resin other than an acrylic adhesive, a plasticizer, 1

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to 4 w/w % of tulobuterol as an active ingredient and 0.1 to 3 w/w % of a higher fatty acid as a drug-release controlling agent on a backing.

Hoffmann teaches a transdermal therapeutic system comprising tulobuterol (reading on the tulobuterol of claim 1) in a matrix containing at least one polystyrene-1,3-diene-polystyrene block copolymer (reading on the rubber of claim 1) (see col. 2, lines 55-58) on a backing layer (reading on the backing of claim 1) (see col. 3, line 2). The adhesive matrix may further contain aliphatic hydrocarbon resins (reading on the adhesive resins of claims 1, 2, and 4) (see col. 3, line 41), mineral oil (reading on the higher fatty acid and C₁₁₋₂₂ fatty acid of claims 1 and 3 (see col. 3, line 62), and glycerol, (reading on the plasticizer of claims 1 and 2) (see col. 3, line 62).

Acrylic adhesives are not required by the Hoffmann invention and are not disclosed in any of the examples.

Hoffmann explains that the disclosed invention is beneficial in that it provides safe dosage of active substance with optimal release rate and tolerance (see col. 2, lines 51-52).

Example 2 of Hoffmann discloses 2% tulobuterol and Example 5 discloses 2.5% tulobuterol, both overlapping with the concentration range recited in claim 1. Example 2 discloses 22% adhesive (copolymers of diolefins and olefins), Example 2a discloses 57% adhesive, and Example 5 discloses 48% adhesive, all overlapping with the concentration range recited in claim 2. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists.

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In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Example 2a discloses 38% rubber (styrene-isoprene-styrene block copolymer). A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). See MPEP 2144.05.

Hoffmann does not disclose percentages for mineral oil and glycerol, however it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges. Higher fatty acids and plasticizers in concentrations overlapping with those being claimed are recognized by the art as result effective variables. Higo teaches C₁₁₋₂₂ fatty acids at a concentration of 0.01-20% (see col. 4, line 64 and col. 5, line 24) and plasticizers at a concentration of 10-60% (see col.

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4, line 52). Stroppolo teaches plasticizers (e.g. polyethylene glycols) at a concentration of 4-20% (see col. 4, line 53). Higo teaches a percutaneous patch formulation for releasing, *inter alia*, tulobuterol (see col. 3, lines 39 and 58). Stroppolo teaches a transdermal therapeutic system for releasing, *inter alia*, tulobuterol (see col. 4, line 35). Neither Higo nor Stroppolo require acrylic adhesives and do not disclose them in any of the examples. Additionally, Higo teaches rubber at a concentration of 15-60% (see col. 3, line 64 – col. 4, line 9), which overlaps with the concentration recited in claim 2.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to prepare a patch consisting of a rubber, an adhesive resin other than an acrylic adhesive, a plasticizer, tulobuterol, and a higher fatty acid, as taught by Hoffmann in view of Stroppolo, further in view of Higo. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides safe dosage of active substance with optimal release rate and tolerance, as explained by Hoffmann (see above).

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615